Sanaria is a biotechnology company developing vaccines protective against malaria.

SANARIA, INC.

It may seem hard to top working on the Human Genome Project, but for Dr. Stephen L. Hoffman, Sanaria founder, that was just one step towards helping to eradicate malaria. Annually, malaria caused by Plasmodium falciparum causes greater than 200 million clinical cases and approximately 0.5 million deaths, is responsible for loss of greater than 1% of Gross Domestic Product in Africa, and is a serious concern for travelers and military personnel. An effective vaccine could have a dramatic impact on the disease - Sanaria is dedicated to the production of whole parasite vaccines protective against malaria, as well as related products for use in malaria research.

PHASE III SUCCESS
The company's lead product is Sanaria® PfSPZ Vaccine, which is currently undergoing clinical evaluations at two study sites in the United States, and in Mali, Kenya, Tanzania, Burkina Faso, and Germany.

AGENCIES
NIH

SNAPSHOT
In early trials Sanaria's vaccine proved effective in preventing malaria caused by *Plasmodium falciparum*—and is proving to be the safest and most effective malaria vaccine candidate to date.

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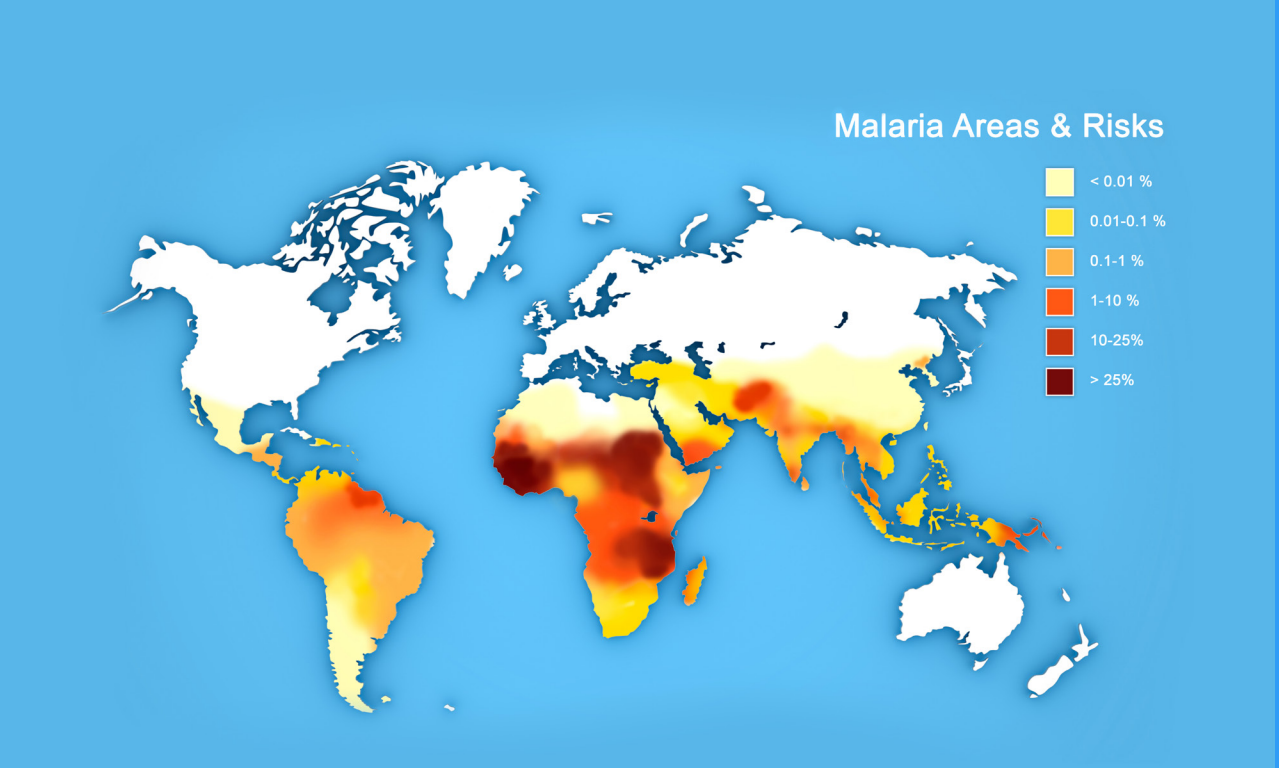
The company's lead product is Sanaria® PfSPZ Vaccine, which is currently undergoing clinical evaluations at two study sites in the United States, and in Mali, Kenya, Tanzania, Burkina Faso, and Germany.. It will soon be further tested in Equatorial Guinea.

Approximately $220 million has been invested in Sanaria's malaria vaccine development effort. The company is working to secure the additional funds to optimize and expand manufacturing in support of its multi-stage clinical development plan, receive licensure from the FDA and other regulatory authorities, launch the vaccine as a commercial product, and demonstrate that it can be used to eliminate P. falciparum malaria from defined areas.

While working at Celera Genomics as senior vice president of Biologics, Dr. Hoffman organized sequencing of the genome of the most important Anopheles mosquito responsible for transmitting malaria in Africa, an effort funded by an NIAID, NIH grant. Several days after resigning from Celera in July 2002 to found Sanaria Inc. with his son Alexander, he submitted a Small Business Innovation Research (SBIR) grant to NIAID, NIH, which was funded 11 months later, and enabled Dr. Hoffman, Alexander, and one other employee to move to their first facility. This 800 square foot space in Rockville, MD was described in National Geographic in 2007 as being in "a dismal mini-mall in suburban Maryland." Dr. Hoffman learned the SBIR grant writing process during the next few years, while applying for and receiving more SBIR awards. Utimately three key SBIR awards provided the foundation for the vaccine's development and have left Dr. Hoffman and his team with a deep appreciation for the SBIR program.



Malaria is an infectious disease that kills 0.6-1 million people each year and sickens hundreds of millions more.

"I believe that for the kind of research and development that we do, particularly in a disease with 2 bottom lines – billions of individuals exposed in the developing world and millions of US travelers, SBIR is a national treasure. The vision of the program is really something tremendous. Having the federal government partnership and support to do the job has dramatic returns for our country and the world," said Dr. Hoffman.

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DR. STEPHEN L. HOFFMAN
FOUNDER

Malaria is the most important parasitic disease in the world. Sanaria's goal is to develop a vaccine that can be used to immunize the entire population in geographically defined areas to halt transmission and eliminate malaria. Because of the expected high level efficacy the vaccine will also be used to prevent malaria in individuals (diplomats, aid workers, military personnel, workers, tourists) who travel from areas without malaria to areas with malaria. Scientists have tried to develop modern, recombinant "sub-unit" malaria vaccines for years, and it has been difficult. In fact, there are only a few recombinant protein vaccines on the market for any disease, and no vaccines based on synthetic peptides, recombinant viruses, recombinant bacteria, or DNA plasmids. Clinical trials have now shown that protection using the Sanaria vaccine lasts for at least 14 months, and is effective against different strains of P. falciparum. The level of protection in some studies has been as good as,the protection afforded by any vaccine for any disease on the world's markets, and far better than the protection afforded by any experimental malaria vaccine under development.

"Thus, our starting point is with an immunogen that has already been shown to be effective, not a technology or platform that has the "potential" to be effective," notes Dr. Hoffman. "We're the only company focused only on malaria, only one major pharmaceutical company has invested significantly in malaria vaccine development . Most other efforts are focused only on young children. Our goal is to vaccinate all people in vulnerable areas."

Sanaria has moved towards a licensing model for its growth and is conducting on-going clinical trials, on three continents while expanding its US presence. Growing from two to more than 45 employees and moving its headquarters to the Alexandria Real Estate Life Sciences and Translational Research Center in the Shady Grove Life Sciences Center (Rockville), located in the heart of Maryland's Biotechnology Corridor. The facility includes a custom-designed and constructed, dedicated Clinical Manufacturing Facility for producing Sanaria's attenuated malaria parasite vaccine, the only manufacturing facility of its type in the world.

In addition to the novel science behind Sanaria's vaccine, Dr. Hoffman credits working closely with the SBIR program and project managers at NIAID with much of the company's success.

"They can help you focus on what's important. Find those people and get as much information as you can, they're great people and have a wealth of knowledge."

Dr. Hoffman also sees many benefits in his company's interactions with the local community. He serves on the Tech Council of Maryland Board of Directors and interacts closely with colleagues from the University of Maryland and other groups in the area, particularly those from NIAID, NIH, and from the DoD.

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